

**REMARKS**

**I. STATUS OF THE APPLICATION**

Claims 1-28 were filed with the original application. In response to the Examiner's Restriction Requirement in the Office Action mailed March 13, 2006, the Applicants cancelled claims 1-13, and 20-28, and added claims 29-38. In the present Response to the Office Action mailed May 26, 2006 the Applicants have amended claims 14, 15, 29-31, 37 and 38. Claims 16-19, and claim 33 have been cancelled.

In the Office Action of May 26, 2006 the Examiner has made 5 rejections. The currently pending rejections are:

- 1.) Claims 14-19 and 29-38 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention.
- 2.) Claims 14, 15, 29 and 30 are rejected under 35 U.S.C. §102(b) as being anticipated by Muddiman *et al.* (Anal. Chem. (1997) 69:1543-1549) (hereinafter "Muddiman, 1997") as evidenced by Muddiman *et al.* (Anal. Chem (1996) 68:3705-3712) (hereinafter "Muddiman, 1996").
- 3.) Claims 17, 18, 31, 32, 34, 35, 37 and 38 are rejected under 35 U.S.C. §103(a) as being unpatentable over Muddiman *et al.* (Anal. Chem. (1997) 69:1543-1549) (hereinafter "Muddiman, 1997") as evidenced by Muddiman *et al.* (Anal. Chem (1996) 68:3705-3712) (hereinafter "Muddiman, 1996") in view of Nakao *et al.* (J. Clin Microbiol. (1997) 35(7):1651-1655) (hereinafter "Nakao").
- 4.) Claims 16 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over Muddiman *et al.* (Anal. Chem. (1997) 69:1543-1549) (hereinafter "Muddiman, 1997") as evidenced by Muddiman *et al.* (Anal. Chem (1996) 68:3705-3712) (hereinafter "Muddiman, 1996") in view of Franzen (U.S. 6, 180, 372) (hereinafter "Franzen").

- 5.) Claims 17-19, 31, 32 and 34-38 are rejected under 35 U.S.C. §103(a) as being unpatentable over Muddiman *et al.* (Anal. Chem. (1997) 69:1543-1549) (hereinafter “Muddiman, 1997”) as evidenced by Muddiman *et al.* (Anal. Chem (1996) 68:3705-3712) (hereinafter “Muddiman, 1996”) in view of Nishikawa (FEMS Microbiol. Letters (1999) 178:13-18) (hereinafter “Nishikawa”).

## **II. STATUS OF THE AMENDMENTS**

In the present Amendment and Response to Office Action of May 26, 2006 the Applicants herein amend claims 14, 15, 29-31, 37 and 38, and cancel claims 16-19 and claim 33. The Applicants note that the amendments and cancellation of claims presented herein are made without acquiescing to any of the Examiner’s arguments or rejections. The amendments of claims presented herein are made solely for the purpose of expediting the patent application process in a manner consistent with the U.S. Patent and Trademark Office’s Patent and Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the amended claims (or similar claims) in the future.

Therefore, claims 14, 15, 29-32 and 34-38 are currently pending in the application.

## **III. PRIORITY**

In the Office Action of May 26, 2006 the Examiner notes:

“It is noted that the patent application 09/798,007, does not teach VNTR. A word search of VNTR or variable number did not yield any results in 09/798,007.

Therefore, claims 16 and 33 do not receive priority to that application.” (Office Action of May 26, 2006, page 2.)

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

Claims 16 and 33 are cancelled in the present Amendment and Response to the Office Action of May, 2006, thereby rendering the Examiner's priority analysis moot with regard to these claims. The Applicants note that cancellation of claims 16 and 33 herein does not disclaim either their subject matter or determination of their priority.

#### **IV. STATUS OF THE REJECTIONS**

##### **A. The Claims are Definite**

In the Office Action of May 26, the Examiner notes:

“Claims 14-19 and 29-38 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as their invention.” (Office Action of May 26, 2006, page 2).

Accordingly, the following amendments to the claims have been made:

The repeated word “thereby” has been deleted from the second to last line of claims 14 and 31.

Dependency of claims 29-30 upon cancelled claim 1 has been amended to pending claim 14.

The definite article “The” at the beginning of claim 31 has been amended to the article “A”.

The Applicants wish to thank the Examiner for identifying these typographic errors.

In turn, “said” has been substituted for “the” in claims 15, 30 and 38, “first and second” has been deleted from claims 29 and 37, “at least one” has been substituted for “a” in claims 15 and 32, and “The” has been substituted for “A” in claim 38.

As well, the Examiner notes:

“Claim 16 is indefinite because it involves the use of VNTR sequences for genotyping, but depends on claim 14, which uses rRNA sequences for

genotyping. As the specification shows on page 38, in example 15, VNTR analysis involves loci that are not the ribosomal sequences. Thus, it is indefinite what is being analyzed in claim 16 since it cannot be the rRNA from claim 14, but no other target is provided.”

Claims 17-19 are indefinite for essentially the same reason as claim 16. These claims are even further from the rRNA sequences used in claim 14, with claim 17 using a “pathogenicity factor”, claim 18 limiting that factor to a “pathogenicity island” a “virulence marker” or a “toxin compound”, and claim 19 referring to a toxin gene inserted by genetic engineering. These claims are inconsistent with claim 14.” (Office Action of May 16, 2006, pages 3-4)

In order to further the prosecution of the present case, while not acquiescing to the Examiner’s argument, and retaining the right to prosecute the original claims (or similar claims) in the future, the Applicants herein cancel claims 16-19. The Applicants note that the amendments and cancellations of claims presented herein are made without acquiescing to any of the Examiner’s arguments or rejections. The amendments and cancellations of claims presented herein are made solely for the purpose of expediting the patent application process in a manner consistent with the U.S. Patent and Trademark Office’s Patent and Business Goals (PBG),<sup>2</sup> and without waiving the right to prosecute the amended claims (or similar claims) in the future.

**B. The Claims Are Not Anticipated by Muddiman, 1997 As Evidenced by Muddiman, 1996.**

In the Office Action of May 26, 2006 the Examiner notes:

“Claims 14, 15, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Muddiman et al. (1997) 69:1543-1549) as evidenced by Muddiman et al. (Anal. Chem (1996) 68:3705-3712).” (Office Action of May 26, 2006, page 3).

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<sup>2</sup> 65 Fed. Reg. 54603 (Sept. 8, 2000).

The Federal Circuit has stated the relevant analysis for anticipation as follows:

"A claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference."<sup>3</sup>

The Applicants respectfully submit that neither of the references cited by the Examiner teach each and every element as set forth in the claims.

Claim 14 has been amended to recite that the first and second members of a primer set hybridize to conserved regions within a single gene. Claim 14 has also been amended to recite comparing the base composition of at least one bioagent to the base compositions of 8 or more bioagents. Muddiman, 1997 does not teach either of these elements, nor does Muddiman, 1996 teach either of these elements.

The Applicants respectfully direct the Examiner's attention to page 3708, column 1 paragraph 2 of the Muddiman, 1996 reference. Here Muddiman, 1996 states that PCR primers were designed to amplify the spacer region between the 16S and the 23S rRNA genes. Figure 1. and column 2 of Muddiman, 1996 describe priming and amplifying this non-gene region. Moreover, Muddiman, 1997 does not remedy this defect. Muddiman, 1997 relies upon the amplification of the spacer region for generating PCR amplicons of the listed *Bacillus* species. An element of currently pending claim 14 is that the primer pairs hybridize with a nucleic acid that encodes a ribosomal RNA. This is not the spacer region between two genes, as taught by Muddiman, 1996. Neither Muddiman, 1996 nor Muddiman, 1997 teaches this element. Because claims 15, 29 and 30 depend on claim 14, and therefore include all limitations of claim 14, these dependent claims are not anticipated by Muddiman.

In view of the above, the Applicants respectfully request that this rejection be withdrawn.

**C. Rejections under 35 U.S.C. §103(a)**

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<sup>3</sup> *Verdegaal Bros. V. Union Oil of California*, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987).

A *prima facie* case of obviousness requires the Examiner to cite to a reference which a) discloses all the elements of the claimed invention, b) suggests or motivates one of ordinary skill in the art to combine the claim elements to yield the claimed invention, and c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements negates a finding of a *prima facie* case and, without more, entitles the Applicants to allowance of the claims in issue. (MPEP)

The Applicants assert that none of the Examiner's references, alone or in combination, disclose all elements of the claimed invention.

**1. Muddiman, 1997 As Evidence by Muddiman, 1996 In View of Nakao Does Not Render the Claims Obvious**

The Examiner has rejected claims 17, 18, 31, 32, 34, 35, 37 and 38 under 35 U.S.C. §103(a) as being unpatentable over Muddiman, 1997 as evidenced by Muddiman, 1996 in view of Nakao. Claims 17 and 18 have been cancelled, thereby rendering moot the Examiner's rejections of claims 17 and 18.

Claim 31 has been amended to recite that the first and second members of a primer set hybridize to conserved regions within a single gene. Claim 31 has also been amended to recite comparing the base composition of at least one bioagent to the base compositions of 8 or more bioagents. Neither Muddiman, 1997 nor Muddiman, 1996 teaches the primers of the present invention. Nor does either of the Muddiman references teach comparisons with 8 or more bioagents. Nakao, for example, does not teach the identification of base compositions, does not teach mass spectroscopy, and does not teach comparisons with the base compositions of 8 or more bioagents.

The Applicants respectfully note that the Examiner's references both individually and in combination fail to teach all elements of claim 31, or of claims that are dependent thereupon. Thus, the Examiner's references fail to establish *prima facie* obviousness of the claims. In order to advance prosecution of this case, the Applicants hereby

incorporate the enclosed declaration under 37 C.F.R. §1.132 by Dr. Steven Buchsbaum.<sup>4</sup>

In his declaration, Dr. Buchsbaum notes that there was no motivation, suggestion or teaching in the prior art for combining broad range priming with molecular mass measurements, and further Dr. Buchsbaum notes the unexpected success of the technology.

In view of the above, the Applicants respectfully request that this rejection be withdrawn.

**2. Muddiman, 1997 As Evidence by Muddiman, 1996 In View of Franzen Does Not Render the Claims Obvious**

The Examiner has rejected claims 16 and 33 under 35 U.S.C. §103(a) as being unpatentable over Muddiman, 1997 as evidenced by Muddiman, 1996 in view of Franzen. Claims 16 and 33 are cancelled in the present Amendment and Response to the Office Action of May 26, 2006, thereby rendering moot the Examiner's rejection of claims 16 and 33.

**3. Muddiman, 1997 As Evidence by Muddiman, 1996 In View of Nishikawa Does Not Render the Claims Obvious**

The Examiner has rejected claims 17-19, 31, 32 and 34-38 under 35 U.S.C. §103(a) as being unpatentable over Muddiman, 1997 as evidenced by Muddiman, 1996 in view of Nishikawa. Claims 17-19 have been cancelled, thereby rendering moot the Examiner's rejections of claims 17-19.

Claim 31 has been amended to recite that the first and second members of a primer set hybridize to conserved regions within a single gene. Claim 31 has also been amended to recite comparing the base composition of at least one bioagent to the base compositions of 8 or more bioagents. Neither Muddiman, 1997 nor Muddiman, 1996 teaches the primers of the present invention. Nor does either of the Muddiman references

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<sup>4</sup> This Declaration was submitted to the United States Patent and Trademark Office in the prosecution of Application No.: 10/156,608 now entered into allowance.

teach comparisons with 8 or more bioagents. Nishikawa, for example, does not teach the identification of base compositions, does not teach mass spectroscopy, and does not teach comparisons with the base compositions of 8 or more bioagents.

The Applicants respectfully note that the Examiner's references both individually and in combination fail to teach all elements of claim 31, or of claims that are dependent thereupon. Thus, the Examiner's references fail to establish *prima facie* obviousness of the claims. In order to advance prosecution of this case, the Applicants hereby incorporate the enclosed declaration under 37 C.F.R. §1.132 by Dr. Steven Buchsbaum. In his declaration, Dr. Buchsbaum notes that there was no motivation, suggestion or teaching in the prior art for combining broad range priming with molecular mass measurements, and further Dr. Buchsbaum notes the unexpected success of the technology.

In view of the above, the Applicants respectfully request that this rejection be withdrawn.

## **V. DOUBLE PATENTING**

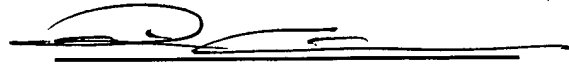
The Examiner has provisionally rejected claims 14-19 and 29-38 under the judicially created doctrine of obviousness-type double patenting over claims 59, 60, 62, 63, 66, 69-76 and 79-94 of Application 10/156,608. Claims 14-19 and 29-38 are also provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10, 14, 17, and 28-44 of co-pending application 10/660,996. Claims 16-19 and claim 33 are cancelled in the present Amendment and Response to the Office Action of May 26, 2006, thereby rendering the Examiner's rejections moot with regard to these claims. A terminal disclaimer with regard to claims in pendency in the present application and to co-pending applications 10/156,608 and 10/660,996 is filed herewith.



**CONCLUSION**

All grounds of rejection of the Office Action of May 26, 2006 have been addressed, and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicant's claims as amended should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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